REMARKS

Claims 1-8 were previously pending in this application. Claims 9-14 were previously withdrawn. No new claims have been added. As a result, claims 1-8 are pending for examination with claim 1 being independent. No new matter has been added.

REJECTIONS UNDER 35 U.S.C. 112

Claims 1-8 were rejected under 35 U.S.C. 112, first paragraph as not enabled. Applicant respectfully disagrees with the Examiner's assertion that undue experimentation would be necessary in order to practice the invention as recited in claims 1-8.

According to one embodiment of the invention, a subject's ability to control appetite may be affected by capillary rarefaction/mitochondria depletion. (Present application, page 33, lines 1-2.) A large part of the regulation of appetite is mediated through the brain, and capillary rarefaction may cause an adequate blood concentration of "nutrients" (or marker compounds proportional to "nutrients") to be interpreted as insufficient. (Present application, page 33, lines 12-14.) Without being bound by any particular theory, it may be that subjects who cannot control their appetite may simply have too long a path between their capillaries and the brain cells that trigger appetite. (Present application, page 33, lines 15-17.) It may be the positive effects of exercise on obesity could be mediated through nitric oxide mediated angiogenesis and that a resultant greater neuron energy reserves my suppress appetite. (Present application, page 34, lines 17-19). This is further supported by the application of AAOB to produce nitric oxide to the inventor for over a year in which the inventor noted a marked reduction in appetite ultimately resulting in a weight loss of about 30 pounds over a year. (Present application, page 34, lines 20-24.)

As noted in the specification, applying ammonia oxidizing bacteria to the surface of a subject produces nitric oxide which can diffuse into the subject. (Present application, page 7, lines 30-32.) Upon reading the present application, one skilled in the art would have understood that the application of any amount of ammonia oxidizing bacteria to a surface of a subject would provide nitric oxide at the surface of the subject, and that any or all of the nitric oxide generated may be available to the subject. Although the Examiner asserted that the specification fails to disclose the amount of bacteria would be enough to diffuse into the subject, those skilled in the

art, based on knowledge of transdermal delivery of nitric oxide and the formation of nitric oxide by ammonia oxidizing bacteria would be able to discern an appropriate dosage without undue experimentation in cooperation with one another. (See MPEP 2164.01(c).) If two distinct technologies are relevant to an invention, then the disclosure will be adequate if a person of ordinary skill in each of the two technologies could practice the invention from the disclosure. (See MPEP 2164.05(b)).

Further, the production of nitric oxide on the surface of a subject is limited by the amount of ammonia and urea released by the subject or available at the surface of the subject. Therefore the quantity of bacteria only reflects the rate of the conversion, not the extent.

Furthermore, in one aspect of the invention, the ammonia oxidizing bacteria applied to the surface of a subject may grow and reproduce on the surface of the subject, which may therefore increase the level of nitric oxide at the surface of the subject. As noted in the present application, the ammonia oxidizing bacteria may have the ability to survive and grow in human sweat; the ability to survive and grow under conditions of high salt concentration; and the ability to survive and grow under conditions of low water activity. (Present application, page 8, lines 3-10.) As such, no undue experimentation would be required by those skilled in the art to practice the invention as claimed and withdrawal of this rejection is therefore, respectfully requested.

Claims 1-8 were rejected under 35 U.S.C. 112, second paragraph as being indefinite.

Claim 1 has been amended to recite, in part, applying ammonia oxidizing bacteria to a surface of the subject to form a compound selected from the group of nitric oxide a nitric oxide precursor, and combinations thereof, and treating the subject with the compound. As noted in the specification, the term "treat" is used to mean prevent or retard the onset of a disease or disorder as well as to retard or stop the progression of disease or disorder after its onset, or to reduce any symptoms commonly associated with the disorder, even if those symptoms do not reach the threshold for clinical disease. (Present application, page 6, lines 14-17.) In claim 1, the non-elected species of aging and retarding due to aging have been added to the step of identifying for agreement with the preamble.

The language of claim 2 has been amended in accordance with the Examiner's suggestion.

With respect to claim 3, the phrase "an effective amount" would be understood by those skilled in the art. Upon reading the present application, one skilled in the art would have understood that the application of any amount of ammonia oxidizing bacteria to a surface of a subject would provide nitric oxide at the surface of the subject, and that any or all of the nitric oxide generated may be available to the subject for treatment of a disorder. Although the Examiner asserted that the specification fails to disclose a particular amount of bacteria, those skilled in the art, based on knowledge of transdermal delivery of nitric oxide and the formation of nitric oxide by ammonia oxidizing bacteria would be able to discern an appropriate dosage without undue experimentation in cooperation with one another. (See MPEP 2164.01(c).) If two distinct technologies are relevant to an invention, then the disclosure will be adequate if a person of ordinary skill in each of the two technologies could practice the invention from the disclosure. (See MPEP 2164.05(b)).

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Applicant disagrees with the Examiner's assertion that claim 5 is indefinite. According to the specification, the subject is defined as a human or vertebrate animal. (Present application, page 6, lines 11-13.) As such, skin and hair is an appropriate surface of the subject.

Accordingly, withdrawal of these rejections is respectfully requested.

REJECTIONS UNDER 35 U.S.C. 102(b)

Claims 1 and 2 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,297,173 to Hikuma et al. (hereinafter Hikuma).

Hikum fails to disclose each and every element of independent claim 1. Hikuma is directed to a method and sensor for determining ammonia and discloses culturing *Nitrosomonas Europaea* in a laboratory. Hikuma fails to disclose, teach, or suggest applying ammonia oxidizing bacteria to the subject to form a compound selected from the group of nitric oxide a nitric oxide precursor, and combinations thereof, and treating the subject with the compound as recited, in part, in independent claim 1. As such, independent claim 1 is not anticipated by Hikuma. Claim 2 depends directly from claim 1 and is not anticipated by Hikuma for at least the same reason. Withdrawal of this rejection is, therefore, respectfully requested.

DOUBLE PATENTING REJECTION

Claims 1-8 were provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 and 3-8 of co-pending application No. 10/332,933.

Amended independent claim 1 is patentably distinct from the claims of co-pending application No. 10//332,933 (the '933 application). The claims of the '933 application are directed to a method of applying ammonia oxidizing bacteria to a subject. Because the methods of the '933 application do not address the treatment of a subject who has developed or is at risk of developing obesity, one skilled in the art would not have understood that a treatment for obesity may include the application of ammonia oxidizing bacteria to a surface of the subject. Because the claims of the '933 application do not address a relation between nitric oxide and obesity, one skilled in the art would not have understood that ammonia oxidizing bacteria may be used to form nitric oxide to treat obesity.

Moreover, one skilled in the art of treating obesity would not have considered utilizing the ammonia oxidizing bacteria. As such, amended claim 1 and dependent claims 2-8 are patentably distinct in view of claims 1 and 3-8 of the '933 application. Withdrawal of these rejections is, therefore, respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, reconsideration is respectfully requested. This application should now be in condition for allowance; a notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not

in condition for allowance, the Examiner is requested to call the Applicant's attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, please charge any deficiency to Deposit Account No. 50/2762.

Respectfully submitted,
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